(a) The Director and Deputy Director, Center for Drugs and Biologics (CDB).

(b) For drugs assigned to their respective offices, the Directors and Deputy Directors of the Offices of: Drug Research and Review and Biologics Research and Review, CDB.

(c) For drugs assigned to their respective divisions, the Directors and Deputy Directors of the Divisions within the Offices of Drug Research and Review and Biologics Research and Review, CDB.

Dated: January 20, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-1502 Filed 1-22-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 357

[Docket No. 79N-0378]

Anthelmintic Drug Products for Over-the-Counter Human Use; Final Monograph; OMB Approval of Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Office of Management and Budget (OMB) has approved the collection of information requirement concerning its final rule on over-the-counter (OTC) anthelmintic drug products. The agency is amending that regulation to reflect OMB's approval.

EFFECTIVE DATE: February 2, 1987.

FOR FURTHER INFORMATION CONTACT: William E. Gilberton, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 1, 1986 (51 FR 27756), FDA issued a final rule in the form of a final monograph effective February 2, 1987 establishing conditions under which OTC anthelmintic drug products (products that destroy pinworms) are generally recognized as safe and effective and not misbranded. In that document (51 FR 27758-27759), FDA announced that it had submitted the final rule to the Office of Management and Budget (OMB) for approval of the collection of information requirement contained in § 357.152.

OMB has approved the collection of information requirement under OMB control number 0910-0232. This document announces OMB's approval and amends the regulation to reflect that approval.

Because this amendment is nonsubstantive, notice and public procedure are unnecessary (5 U.S.C. 553 (b)(B) and (d)).

List of Subjects in 21 CFR Part 357

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 357 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. In § 357.152 by adding a parenthetical statement at the end of the section, to read as follows:

§ 357.152 Package inserts for anthelmintic drug products.

* * * * *

(Collection of information requirement approved by the Office of Management and Budget under number 0910-0232)

Dated: January 15, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-1501 Filed 1-22-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of 1-Methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place the narcotic substances, 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This action is based on findings made by the DEA Administrator that both MPPP and PEPAP meet the statutory criteria for inclusion in Schedule I of the CSA. These findings are in agreement with the independent reviews and evaluations of relevant data conducted by both DEA and the Assistant Secretary for Health, Department of Health and Human Services. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I will be applicable to the manufacture, distribution, importation and exportation of MPPP and PEPAP.

EFFECTIVE DATE: January 23, 1987.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: MPPP and PEPAP are potent analogs of meperidine, a Schedule II synthetic narcotic analgesic. Produced in clandestine laboratories, MPPP and PEPAP have been identified in the illicit drug traffic and MPPP in particular has been associated with the production of drug-induced Parkinson's disease in a number of users.

Based on the data available to him in 1985, the DEA Administrator determined that emergency scheduling of MPPP and PEPAP into Schedule I of the CSA was necessary to avoid an imminent hazard to the public safety. Therefore, in a **Federal Register** notice (50 FR 28098-100) dated July 10, 1985, the DEA Administrator, pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h), placed MPPP and PEPAP into Schedule I of the CSA for one year effective on August 12, 1985. The temporary scheduling of MPPP and PEPAP was extended until February 12, 1987 in a subsequent **Federal Register** notice (51 FR 28695-6).

Following an independent review of the relevant data on MPPP and PEPAP by DEA and a scientific and medical evaluation of these substances by the Assistant Secretary for Health, the DEA Administrator, pursuant to 21 U.S.C. 811, proposed the permanent placement of MPPP and PEPAP into Schedule I of the CSA (August 11, 1986, 51 FR 28725-6). Interested parties were given until September 10, 1986 to submit comments or objections in writing regarding this proposal. During this 30-day period, DEA did not receive any comments or objections to the proposed scheduling action.

Based upon the investigations and review conducted by DEA and upon the scientific and medical evaluation and recommendation of the Assistant